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14. ABSTRACT

This report represents the first year in a multi-year effort to improve outcomes in patients with traumatic brain injury (TBI). This project will utilize human and animal models in an effort first to identify what factors are most important in determining outcome from TBI and secondly to test new techniques in patient care. Year 1 focused on development of an infrastructure for assessment of TBI patients, development of a protocol to advance our understanding of the inflammatory process which follows TBI and creation of a basic science model of penetrating brain trauma. Hiring and assignment of staff purchase and development of need equipment, and protocol and database development were the primary focus of efforts.

Work was initiated on the development of the Brain Resuscitation Registry to provide structure and linkage capabilities for data collection and outcome reporting.

Three sub-projects were also developed, two human uses and one animal model. By the close of Year 1, institutional review board approval for all three sub-projects had been obtained and subject recruitment and data collection initiated for the human use sub-projects.

15. SUBJECT TERMS
Traumatic Brain Injury (TBI); vital signs; cytokines; pre-hospital care; polytrauma

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INTRODUCTION

Traumatic Brain Injury (TBI) is the primary cause of trauma mortality in both civilian and military populations, a major source of long-term disability world-wide and a substantial independent cause of death in the U.S. The dominance of TBI in trauma epidemiology is due to our inability to treat primary central nervous system injury and the realization that the phenomenon of secondary brain injury (pathology at the metabolic, cellular, vascular and tissue levels) begins within seconds after the primary trauma and plays a profound role in the subsequent evolution of TBI. The first phase of this multi-year effort to improve outcomes in TBI patients focused on developing the infrastructure necessary to associate elements of care for the TBI patient with specific and relevant outcomes, including establishment of a centralized Brain Resuscitation Registry for data capture, deployment of equipment to capture continuous pre-hospital and in-hospital vital signs, develop a protocol to examine the contribution of inflammatory cytokines after TBI and to develop an animal model of penetrating brain trauma.

BODY

This is the annual report for Year 1 of a multi-year project. Table 1 below reflects the Project Milestones Timeline adjusted based on the actual funding award date of September 17, 2007. Start and finish date columns reflect target timelines while subsequent columns reflect actual task completion dates. Research progress is further summarized by the itemized Statement of Work Tasks following the table.

Table 1: Timeline

Activity name	Target Completion		Actual Completion		
	State Date	Finish Date	2007+	2008	2009
Patient recruitment and monitoring					
**** IRB approvals**	1-Oct-07	31-Jan-08		Vital signs 02-Apr-08 Cytokines 29-Jul-08	
**** hiring and training of staff**	1-Oct-07	31-Jan-08			
****design and implementation of data collection systems**	1-Oct-07	31-Jan-08			
****patient enrollment**	31-Jan-08				
****data collection**	31-Jan-08				
****data collation and analysis**	1-May-08				
cytokine laboratory					
****identification and training of staff**	1-Oct-07				
****clinical data protocols**	1-Oct-07				
animal model					
****IRB approvals**	1-Oct-07			26-Feb-08	
****final study design**	1-Oct-07				

Implement plans for recruiting and monitoring patients.
Obtain Institutional Review Board (IRB) approval for recruiting and monitoring TBI patients.

Both human sub-projects have received IRB approval from the University of Maryland (UMB), IRB and the USAMRMC ORP, HRPO.

Sub-project 1: Vital Signs Data in Trauma Patients

This project was approved by UMB, IRB and USAMRMC ORP, HRPO upon continuing review on 2/21/08. This study was then re-assigned to the current project "Early Support of Intracranial Perfusion," on 2/26/08.

On 4/2/08 an amendment to the protocol including updating of the consent form, HIPAA form and mailing letter and removal of the clause sending raw data to TATRC for analysis was submitted. This amendment was approved by UMB IRB on 4/14/08 and USAMRMC ORP, HRPO on 4/28/08.

Sub-project 2: Early Support of Intracranial Perfusion – Cytokines

Much of the 2nd and 3rd quarters of Year 1 were spent finalizing the protocol for this sub-project. A draft version of the protocol was submitted to USAMRMC for recommendations on 2/14/08 and comments received 2/20/08. The protocol was initially submitted to UMB IRB on 3/20/08 and approved on 4/23/08. Initial submission to USAMRMC ORP, HRPO occurred 4/24/08 with review and requested revisions received on 6/10/08. The final revised protocol was submitted to UMB IRB on 7/18/08 and simultaneously sent to USAMRMC ORP, HRPO. Approval was received from UMB, IRB on 7/28/08 and USAMRMC ORP, HRPO on 7/29/08 following receipt of UMB IRB approval documents.

During this time emphasis was also been placed on staff recruitment and assignment of designated roles within the research staff for subject recruitment, data collection and analysis, and ongoing monitoring and reporting of study outcomes for the two above sub-projects. Standardized policies and procedures were also developed in anticipation of subject recruitment and will continue to be updated as indicated now that study recruitment has been initiated.

Complete the Brain Resuscitation Registry network architecture

As of February 2007, a secure web-based Trauma Registry containing clinical patient information for trauma patients was established. This application is expanding to include a Brain Resuscitation Registry that will provide all data points necessary to capture vital information as established in our research study protocols.

Currently, several processes have been completed or are in the test phase of development. Links have been established to specialized clinical systems to automate the extraction of patient data needed to profile, enroll, manage and analyze current study patients. Security has been enhanced to restrict patient access based on a user's job responsibilities and study privileges. Study protocols have been centralized and automated allowing for communication between studies to be established. Screens have been added to the Registry

for current trauma patients to allow them to be selected for a study and then manage the abstraction of the subject's clinical data. The Cytokines sub-project is currently testing this process as it utilizes the Registry to manage study subjects.

In development for the Brain Resuscitation Registry are additional application enhancements. A patient screening module is being designed that will allow enrollment of study patients at the bedside. This will provide a real-time census of current study subjects. Processes will be automated to provide tools to evaluate and correct data quality issues such as missing or incorrect subject information. Standard reporting will be developed for managing studies. Ad-hoc reporting and data extraction tools will be incorporated to improve the analysis of study subject data. A help feature will be available to provide researchers with an on-line tutorial for application use and the processes behind the applications. A dictionary of medical terms and laboratory tests will be accessible. Designated researchers will be able to add to and maintain these dictionaries. Help features will be attached to data points to explain the specification and interpretation of data for each field captured. As we move forward in the design of the Brain Resuscitation Registry, processes are continuously being analyzed and incorporated into the application to improve the efficiency and quality of data.

Provide staffing and facilities to monitor patients and collect designated specimens

Sub-project 1: Vital Signs (VS) Data in Trauma Patients

Pre-hospital Vital Signs Data Collection (VSDC) system

During the course of Year 1 emphasis has been placed on the development of equipment and working with pre-hospital providers to expand capabilities to obtain pre-hospital vital signs data. To this end the following tasks have been completed:

1. A total of six additional VSDC PDA (personal data assistant) units have been built for in-flight data collection
2. Work to modify/configure the in-flight VSDC system for the current study
3. Add EICP (Early Support of Intracranial Perfusion) collection to the pre-hospital real-time web feedback for emergency medical personnel
4. Conduct a total of seven meetings with in-flight pre-hospital paramedics on system training and to gather operational feedback
5. Initiate training with research staff on facilitating the collection of pre-hospital VS data and establishment of standard procedures for subject screening, consent and data collection
6. Conduct meetings (4) regarding the expansion of VSDC to ambulance transport. Identification of initial county EMS (emergency medical system) for system testing and deployment
7. Initiate development and reliability testing of ambulance patient monitor data collection system. System to collect trend VS data sets and alarms from patient transport monitors

In-hospital Vital Signs Data Collection (VSDC) system

As a limited system for vital signs data collection was in existence prior to the reassignment of this sub-project to the larger study, emphasis in Year 1 has been on system upgrades and expansion of VSDC capabilities. Following is a summary of key tasks in this

effort:

1. Upgrade of existing in-hospital real-time VSDC system located in the Trauma Resuscitation Unit (12 admission bays and 6 operating bays). Current system is now capable of collecting real-time VS trend data from bedside monitor with 6 second trend data sets
2. Expanded data collection network to cover a total of 54 critical patient bays/beds. This included the process of equipment purchasing, installation and testing. In addition to the previous existing Trauma Resuscitation Unit (TRU) 12 bays and 6 Operating Room (OR) bays, the network covers 12 Neuro-trauma Intensive Care Unit (ICU) bays, 12 Multi-trauma ICU bays, and 12 Neuro-trauma intermediate care unit bays.
   Throughout the process of VSDC network implementation, 5 stages of development, test and deployment are utilized for embedding the correcting system with real-time patient care monitoring to ensure a)no disruption to standard patient care; b) collection of accurate VS data from the patient monitor. The table below (2) describes this process and for full implementation of the 54 bays currently included in the network.

Table 2: VSDC Deployment

	Stages	I	II	III	IV	V
	Stage Definition	System update/ Lab accuracy and reliability test	System installation	System On-Line accuracy and reliability test	Joint review and release for intra-hospital VS data collection	Data Abstraction and Mining
Unit/ Function	Bay/Bed #					
Trauma Resuscitation Unit (TRU)	12	Y1Q1	Y1Q1	Y1Q1	Y1Q1	Y1Q1
Operating Room (OR)	6	Y1Q1	Y1Q1	Y1Q1	Y1Q1	Y1Q1
Neuro-trauma ICU	12	Y1Q1/Y1Q2	Y1Q2	Y1Q2	Y1Q2	Y1Q3
Multi-Trauma ICU	12	Y1Q1/Y1Q2	Y1Q2	Y1Q3	Y1Q3	Y1Q3
Neuro-Trauma Intermediate Care Unit	12	Y1Q2	Y1Q3	Y1Q4	Y1Q4	Y1Q4

3. Investigate the capabilities of the VSDC system to include the brain oxygen monitor (Licox), and testing of the interface with the VSDC network

VSDC System Data Mining

The following steps were undertaken to begin the mining of data collected for this sub-project.

1. Data compression algorithm was selected and applied to both pre-hospital and in-hospital data sets

2. Recruitment of a database programmer for real-time VS data processing and mining
3. Recruitment/assignment of statistician to work with data integrity and prediction models
4. Development and testing of continuous VS data set cleaning, feature abstraction and prediction algorithms
5. Recruitment of graduate research assistant to assist with VS prediction algorithm development
6. On-going meetings to address the logistics of data collection and research initiatives.

In addition to the above tasks, evaluation of on-line system accuracy, traceability and reliability were conducted during the implementation. A brief summary of the tests conducted can be found in Table 3

Table 3: VSDC System testing

Accurate recording of patient monitor VS readings?	Random convenience sample	15 cases 10 key VS readings	100% match between real-time monitor readings and collected VS data sets
Continuously collect same subject VS from pre-hospital to in-hospital?	Random convenience sample	157 cases of pre-hospital air transport selected	157 cases (100%) match of in-hospital record and Trauma Registry data 150 cases (96%) linked between pre and in-hospital continuously recorded VS data sets
Continuously collect same subject VS from TRU to ICU	Random convenience sample	15 cases	100% match between different care unit VS data sets

Subject consent process

Staff training and an enrollment database were established during the third quarter of Year 1 to allow more streamlined tracking of potential study subjects. Procedures for subject consent (both in-hospital and via mailing) and data collection were refined from the previous version of the study.

In June 2008, daily tracking of potential study subjects arriving via selected air transport was initiated and regular attempts to consent subjects during in-patient hospitalization began. Bi-weekly mailings to potential subjects not recruited during their in-patient stay were initiated during the fourth quarter of Year 1. Further refinement of the screening process is on-going and expanding to encompass potential subjects arriving via any transport mechanism in early October 2008.

In the three months since the standardized approach to consenting has been in place, 279 potential subjects have been identified by daily screening. Of those potential subjects meeting enrollment criteria, approximately 20 have been approached during their hospital stay and 14 have consented to study participation. An additional 82 letters requesting consent to participate have been mailed to subjects meeting enrollment criteria and with documented contact information, and 9 additional consents obtained via this process.

Due to this low return on consents obtained, an amendment for a waiver of consent for this study is planned for the first quarter of Year 2 for the following reasons: a) The request to use data that has already been collected as part of routine clinical care for aggregation without identifiers is intrusive for patients and their families already stressed by the traumatic event and admission to the Shock Trauma Center. b) The trauma patient population is generally very transient (i.e. phone numbers and mailing addressed provided on admission are rarely accurate, or the location of first discharge from the hospital) making it impossible to contact most of these patients to obtain consent.

Sub-project 2: Early Support of Intracranial Perfusion – Cytokines

Standardized policies and procedures for recruitment, specimen and data collection were developed throughout the third and fourth quarters of Year 1. The sub-project coordinator was assigned and identified research staff trained on recruitment and specimen/data collection procedures.

Screening for this sub-project was opened on 8/20/08. At the close of Year 1, 25 potential study subjects had been screened but found to not fit enrollment criteria or declined participation. However, within the first 2 weeks of Year 2 three subjects have now been enrolled in this sub-project.

Implement laboratory evaluation of inflammatory cytokines
Provide staffing, equipment, facilities and training to process study cytokine specimens

Sub-project 2: Early Support of Intracranial Perfusion – Cytokines

Standardization of procedures for handling of specimens collected and specimen storage was completed during the fourth quarter of Year 1. A technician was assigned to assist with specimen processing. The assay materials required for processing were identified and ordering of the supply kits undertaken.

Develop an animal model of penetrating brain injury
Coordinated with MRMC research institutions to begin development of this model

Sub-project 3: Characterization of a New Porcine Model of Penetrating Ballistic Brain Injury

This animal use protocol was approved by the UMB IACUC on 9/21/07. It was subsequently submitted to the USAMRMC Animal Care and Use Review Office (ACURO) on 11/27/07. In response to the review by the USAMRMC ACURO, a revised protocol was submitted on 2/25/08 and approved by USAMRMC ACURO on 2/26/08.

Preliminary experiments were performed with antibodies to different markers of inflammation and oxidative stress to determine their suitability for application to both animal models of traumatic brain injury and to serum samples obtained from traumatic brain injury patients.

KEY RESEARCH ACCOMPLISHMENTS

Sub-project 1: Vital Signs Data in Trauma Patients

- Enhanced the pre-flight patient Vital Signs data collection network
- Developed and expanded the in-trauma center VS data collection network to cover all critical care bays (TRU, OR, ICU)
- Developed and deployed a total pre and in-hospital VS data collection network
- Developed a basic VS data mining system to collect, process, and predict patient outcomes
- Established a road map for innovative prediction algorithm development

Sub-project 2: Early Support of Intracranial Perfusion – Cytokines

There are no reportable outcomes at this time. The research is in the early recruitment phase with limited data collection completed.

Sub-project 3: Characterization of a New Porcine Model of Penetrating Ballistic Brain Injury

There are no reportable outcomes at this time. Protocol development is still underway.

REPORTABLE OUTCOMES

a) Presentations:

The following two topics were presented in American Telemedicine Association Annual meeting (April 6-9, 2008) Seattle, WA.

"Challenges in developing real-time in-flight patient vital-signs data collection system"
Peter Hu MS CNE, Christopher Handley MS EMT-P, Steve Seebode, Anne Conway RN MS, Ryan Gens BA, Colin Mackenzie MD, Danny Ho MS, Gregory Defouw MSCS, Phil Davies MS, Douglas Floccare[4] MD MPH,

Real-time Patient Vital Sign Data Collection Network for Trauma Care
Peter F. Hu MS CNE, Colin Mackenzie MD, Richard P. Dutton MD, Grant Bochicchio MD, Kelly Bochicchio RN,MS, Yan Xiao PhD, John Spearman MBA, Thomas Scalea MD.

The following two topics were presented at the 5th Annual Innovations in the Surgical Environment Conference, June 26-27 2008 Baltimore Maryland.

Lesson Learned: Developing In-Flight Patient Vital-Signs Data Collection Network
Peter Hu MS CNE, Christopher Handley MS EMT-P, Ayan Sen MD, Steve Seebode, Anne Conway RN MS, Ryan Gens BA, Betsy Kramer RN, Sean Jordan MHS, EMT-B, Rebecca Webb BA, CCRC , Gregory Defouw MSCS, Phil Davies MS, Danny Ho MS, Yan, Xiao PhD, Colin Mackenzie MD, and Trauma Vital Signs Investigator and Associates (TVSI,TVSRA) Group

Can Pre-Hospital Patient VS Predict Injury and Intervention?
Peter F. Hu MS CNE, Colin Mackenzie MD, Richard P. Dutton MD, Ayan Sen, MD, Douglas Floccare MD, MPH , Grant Bochicchio MD,MPH, Yan Xiao PhD, John Spearman MBA, Thomas Scalea MD.

b) Accepted for presentation:

Continuous prehospital vital signs record identifies increased abnormalities/predicts interventions.
Ayan Sen MD, Peter Hu MS, CNE, Colin Mackenzie MD, FRCA, Sean Jordan EMT-B, Richard Dutton MD, MBA. Program in Trauma, R. Adams Cowley Shock Trauma Center, National Study Center, University of Maryland School of Medicine, Baltimore MD
Accepted for presentation in American Society of Anesthesiologists annual conference October 18-22, 2008, Orlando, FL.

Automatic Pre-Hospital Vital Signs Waveform and Trend Data Capture Fills Quality Management, Triage and Outcome Prediction Gaps
Colin F Mackenzie MB ChB, FRCA, FCCM, Peter Hu MS CNE, Ayan Sen MD, Rick Dutton MD, Steve Seebode BS, Doug Floccare MD, MPH ,Tom Scalea MD
Accepted for oral presentation. American Medical Informatics Association annual symposium Nov 8-12, 2008 Washington DC

Statewide Real-Time In-Flight Trauma Patient Vital Signs Collection System
Peter Hu, MS, CNE, Colin Mackenzie, MD, Richard Dutton, MD, Ayan, Sen, MD, Yan, Xiao PhD, Christopher Handley, MS, EMT-P, Danny Ho MS, Thomas Scalea, MD
Accepted for poster presentation. American Medical Informatics Association annual symposium, Nov 8-12, 2008 Washington DC

c) Publications (Journal or Proceedings):

Hu PF, Handley C, Seebode S, Conway A, Gens Y, Mackenzie C, Ho D, Defouw G, Davies P, Floccare D. **Challenges in Developing Real-Time In-Flight Patient Vital-Signs Data Collection System**. Telemedicine and e-Health. 14(1)105. 2008

Hu PF, Mackenzie CF, Dutton R, Bochicchio GV, Bochicchio K, Xiao Y, Spearman J, Scalea T. **Real-time Patient Vital Sign Data Collection Network for Trauma Care** . Telemedicine and e-Health. 14(1)62. 2008

Lesson Learned: Developing In-Flight Patient Vital-Signs Data Collection Network
Peter Hu MS CNE, Christopher Handley MS EMT-P, Ayan Sen MD, Steve Seebode, Anne Conway RN MS, Ryan Gens BA, Betsy Kramer RN, Sean Jordan MHS, EMT-B, Rebecca Webb BA, CCRC , Gregory Defouw MSCS, Phil Davies MS, Danny Ho MS, Yan, Xiao PhD, Colin Mackenzie MD, and Trauma Vital Signs Investigator and Associates (TVSI,TVSRA) Group. Proceedings of 5th Annual Innovations in the Surgical Environment Conference.

Can Pre-Hospital Patient VS Predict Injury and Intervention?
Peter F. Hu MS CNE, Colin Mackenzie MD, Richard P. Dutton MD, Ayan Sen MD, Douglas Floccare MD, MPH , Grant Bochicchio MD,MPH, Yan Xiao PhD, John Spearman MBA, Thomas Scalea MD. Proceedings of 5th Annual Innovations in the Surgical Environment Conference.

d) Submitted for journal publications and conferences

Automated vital-sign recording identifies more critical episodes than chart abstraction
Peter Hu MS, CNE, Ayan Sen MD, Colin Mackenzie MD, FRCA, Yan, Xiao PhD, Sean Jordan EMT-B, Richard Dutton MD, MBA, Thomas Scalea, MD and Trauma Vital Signs Research Group (TVSG)

Can EMS Protocols be monitored remotely in pre hospital care of Traumatic Brain Injury (TBI)?

Colin Mackenzie MD, FRCA, Peter Hu MS, CNE Ayan Sen MD, Yan, Xiao PhD, Sean Jordan EMT-B, Richard Dutton MD, MBA, Thomas Scalea, MD.
Program in Trauma, R. Adams Cowley Shock Trauma Center, National Study Center, University of Maryland School of Medicine, Baltimore MD

CONCLUSIONS

At the conclusion of Year 1 significant progress has been made toward meeting overall project milestones, and all tasks identified for year 1 initiated and many cases completed. An infrastructure of staff, technology and data management to support the completion of sub-projects and long-term assessment of TBI patients had been outlined and initiated. The robust Brain Resuscitation Registry needed to accomplish the goals of this-multi year project continues to develop and be tested in the context of sub-project 2. Key individuals have been identified for each of the sub-projects and sub-project policies and procedures developed. Recruitment and data collection for the two human sub-projects has been initiated and plans for analysis developing as we move into Year 2. As we move into Year 2, ongoing development of the existing infrastructure will continue, as well as continuous assessment of policies and procedures, data collection processes and outcomes management for the identified sub-projects.

REFERENCES

Literature searches were conducted during Year 1 in preparation for the Cytokines sub-project. Key words utilized included: cerebrospinal fluid, cytokine, inflammation, outcome, TBI, ventriculitis.

Key reference articles identified include:

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APPENDICES

Abstracts Presented:

Lesson Learned: Developing In-Flight Patient Vital-Signs Data Collection Network

Peter Hu MS CNE, Christopher Handley MS EMT-P, Ayan Sen MD, Steve Seebode, Anne Conway RN MS, Ryan Gens BA, Betsy Kramer RN, Sean Jordan MHS, EMT-B, Rebecca Webb BA, CCRC , Gregory Defouw MSCS, Phil Davies MS, Danny Ho MS, Yan, Xiao PhD, Colin Mackenzie MD, and Trauma Vital Signs Investigator and Associates (TVSI,TVSRA) Group

BACKGROUND: Developing a reliable real-time in-flight patient vital-signs data collection system (VSDC) presents many challenges, but is necessary to understand field management issues. We report the challenges and some solutions for design and deployment of such a system.
METHODS: VSDC uses a PDA (HP-iPAQ) to collect real-time patient vital signs (VS) data from a commonly used VS monitor (Propaq-Encore206EL). VSDC can store up to 350 hours (1 GB) of continuous patient VS waveform (ECG at 182 Hz, SpO2/ETCO2 at 90Hz) and numerical trended data (HR/SpO2/ETCO2/NIBP/Temp at 1 Hz) for evaluation, data analysis and data mining.
RESULTS: Challenges: Observed unreliability of consumer grade PDA under high-speed live serial (RS232) data collection; high maintenance; interface design issues; short battery life; PDA required protective field packaging; multi-site field system deployment required effective communication with the field care providers. Solutions: A data interface box was built to improve serial data communication; a real-time error detection, self recovery algorithm corrected the frequent occurrence of PDA power disruptions during field operations; patient monitor connection status, SpO2 and BP value display, and events marker buttons simplified the user interface; a secure web interface for information dissemination, patient information collection, remote training, and user feedback facilitated multi-site deployment. The three VSDC systems in Medevac helicopters which transfer patients tot a major trauma hospital have collected 157 in-flight patient VS data sets with the average case length of 25.9 minutes (1.38 MB filesize).
DISCUSSION: Efforts to build a reliable and user-friendly data collection device is essential to successful system deployment. Remote user training, support and feedback through the web interface were well received. Great support and instant feedback from the STATE police aviation division made the rapid system updates possible. Also, the PDA battery life remains a challenge for long-term service free operation.

Accepted for presentation:

Continuous Prehospital Vital Signs Record Identifies Increased Abnormalities/Predicts Interventions

Ayan Sen MD, Peter Hu MS, CNE, Colin Mackenzie MD, FRCA, Sean Jordan EMT-B, Richard Dutton MD, MBA. Program in Trauma, R. Adams Cowley Shock Trauma Center, National Study Center, University of Maryland School of Medicine, Baltimore MD
Accepted for presentation in American Society of Anesthesiologists annual conference October 18-22 Orlando, FL.

BACKGROUND: In the time-critical phase of pre-hospital trauma care, changes in vital signs (VS) need to be recorded during resuscitation and stabilization. We tested the hypothesis that continuous, automated collection of field VS data identifies more episodes of abnormalities and improves prediction of life-saving interventions (LSI) like endotracheal intubation, tube thoracotomy, blood transfusion etc than the manual method as reported in the trauma registry (TR).
METHODS: Continuous pre-hospital VS (SBP, HR, SpO2) captured by a pre-hospital VS data recorder (VSDR) were assessed retrospectively by 3 independent raters. Inter-rater reliability (IRR) was assessed by Pearson r. Ranges and standard deviations (SD) of values from continuous VS (highest/lowest/ first minute/last minute of collection) were compared to TR VS by paired t-test. Episodes of SBP [<90; <110], HR [>100; 120] and SpO2 [<95; <90] identified in the continuous VS record were compared to TR data by McNemars test . Changes in field Trauma Injury Severity Score (TRISS) and admission TRISS were computed using different VS sources. Probability of abnormal VS predicting a LSI on arrival to trauma center was assessed by univariate analysis and plotting the ROC (Receiver-Operator Curve). Statistical Analysis was conducted using JMP7 (SAS Institute, Cary, NC).
RESULTS: The records of 148 patients collected over a 6 month period were analyzed. The pre-hospital transfer time was 25.5 mins (Range 8- 60 mins). ISS was 9.8 + SD 7.9. IRR was: HR(r = 0.91-0.99), SBP (r=0.97-0.98), DBP= (r=0.95-0.99) and SpO2(r=0.84-0.97) captured in the first minute, last minute and of the highest and lowest VS values. Manually collected prehospital VS were significantly different from automated VS ($p<0.001$). Increased numbers of episodes of abnormal VS ($p<0.001$) were captured by automated VS.[table1]LSI in the pre-hospital phase or on arrival to trauma center were better predicted using combination of abnormal VS from continuous record (area under ROC curve 0.55-0.65) in comparison to TR VS (0.49-0.52). The numbers of patients whose field and admission TRISS were different based on automated versus manually collected of VS were 7 (5%) and 5 (3%), respectively, for the 148 patients analyzed, all due to the additional hypotensive episodes captured by the automated method ($p=0.45$). Majority (60%, n=3/5) of those with worse scores needed life-saving interventions after arrival to the trauma center.
CONCLUSIONS : Prediction of interventions, long-term outcomes and prognostic modeling are improved with continuous automated capture of VS. Major differences in detection of hypoxemia, hypotension and HR increase suggest that prediction possibilities of pre-hospital VS and scores (TRISS) are being missed when TR with intermittent VS data are used.

Summary of Staff, Roles and Percent Effort by Project/Sub-project

Staff Member	Role	% Effort
Thomas Scalea	PI	4.8
Lisa Gettings	Administrator	0
Karen Murdock	Project Manager	54
Colin Mackenzie	Sub-Project PI; Vital Signs study	20
Peter Hu	Co-Investigator	41.5
Steven Seebode	Technical Support	57.4
Reeba Thomas	Coordinator; Vital Signs study	90
Deborah Stein	Sub-project PI; Cytokine study	8
Bizhan Aarabi	Co-Investigator	2
Richard Dutton	Co-Investigator	8
Rebecca Webb	Coordinator; Cytokines study	20
Kaspar Keledjian	Cytokine technician	19.7
Robert Rosenthal	Sub-project PI; Animal model	2
Gary Fiskum	Co-Investigator	24
Madeline Mitrou	Research Nurse	40
Yawei Wang	Research Nurse	40
Leody Bojanowski	Research Nurse	2.5
Margaret Mensa	Research Nurse	20
Marianne Hattan	Research Nurse	90
Keri Volpini	Research Assistant	10
Christine Wade-Mariani	Research Assistant	10
Charles Simpson	Research Assistant	81
Allison Lindell	Research Assistant	100
Robin Cohen	Research Assistant	55
Kristina Clem	Data Entry	83.8
	Statistician	0
Gordon Smith	Epidemiologist	22.88
Chris Handley	EMT Education	7.77
Julie Hazleton	Technician	50
Irena Balan	Post-doctoral Fellow	50

Contract Expenditures to Date

Cost Elements	4th Quarter, Year 1*	Year 1 Total
Personnel	$191,689	$477,416
Fringe Benefits	$30,752	$75,619
Supplies	$2,791	$18,363
Equipment	$0	$22,125
Travel	$0	$1,578
Other Direct Costs	$0	$2,070
Subtotal	*$225,232*	*$597,171*
Indirect Costs	$58,560	$149,512
Fee	$0	$0
Total	$283,792	$746,683

*Includes expenditures through 9/30/08